



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-3408-N]

CLIA Program; Announcement of the Re-Approval of the College of American Pathologists (CAP) as an Accreditation Organization under the Clinical Laboratory Improvement Amendments of 1988

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This notice announces the application of the College of American Pathologists (CAP) for approval as an accreditation organization for clinical laboratories under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) program. We have determined that the CAP meets or exceeds the applicable CLIA requirements. In this notice, we announce the approval and grant CAP deeming authority for a period of 6 years.

DATES: This notice is effective from March 27, 2021 until March 26, 2027.

FOR FURTHER INFORMATION CONTACT:

Cindy Flacks, 410-786-6520.

SUPPLEMENTARY INFORMATION:

I. Background and Legislative Authority

On October 31, 1988, the Congress enacted the Clinical Laboratory Improvement Amendments of 1988 (CLIA) (Pub. L. 100-578). CLIA amended section 353 of the Public Health Service Act. We issued a final rule implementing the accreditation provisions of CLIA on July 31, 1992 (57 FR 33992). Under those provisions, we may grant deeming authority to an accreditation organization if its requirements for laboratories accredited under its program are equal to or more stringent than the applicable CLIA program requirements in 42 CFR part 493 (Laboratory Requirements). Subpart E of part 493 (Accreditation by a Private, Nonprofit

Accreditation Organization or Exemption Under an Approved State Laboratory Program) specifies the requirements an accreditation organization must meet to be approved by CMS as an accreditation organization under CLIA.

II. Notice of Approval of CAP as an Accreditation Organization

In this notice, we approve the College of American Pathologists (CAP) as an organization that may accredit laboratories for purposes of establishing their compliance with CLIA requirements in all specialties and subspecialties. We have examined the initial CAP application and all subsequent submissions to determine its accreditation program's equivalency with the requirements for approval of an accreditation organization under subpart E of part 493. We have determined that the CAP meets or exceeds the applicable CLIA requirements. We have also determined that the CAP will ensure that its accredited laboratories will meet or exceed the applicable requirements in subparts H, I, J, K, M, Q, and the applicable sections of R. Therefore, we grant the CAP approval as an accreditation organization under subpart E of part 493, for the period stated in the DATES section of this notice for all specialties and subspecialties under CLIA. As a result of this determination, any laboratory that is accredited by the CAP during the time period stated in the "DATES" section of this notice will be deemed to meet the CLIA requirements for the listed specialties and subspecialties, and therefore, will generally not be subject to routine inspections by a state survey agency to determine its compliance with CLIA requirements. The accredited laboratory, however, is subject to validation and complaint investigation surveys performed by CMS, or its agent(s).

III. Evaluation of the CAP Request for Approval as an Accreditation Organization Under CLIA

The following describes the process used to determine that the CAP accreditation program meets the necessary requirements to be approved by CMS and that, as such, we may approve the CAP as an accreditation program with deeming authority under the CLIA program. The CAP formally applied to CMS for approval as an accreditation organization under CLIA for

all specialties and subspecialties.

In reviewing these materials, we reached the following determinations for each applicable part of the CLIA regulations:

A. Subpart E--Accreditation by a Private, Nonprofit Accreditation Organization or Exemption Under an Approved State Laboratory Program

The CAP submitted its mechanism for monitoring compliance with all requirements equivalent to condition-level requirements, a list of all its current laboratories and the expiration date of their accreditation, and a detailed comparison of the individual accreditation requirements with the comparable condition-level requirements. We have determined that the CAP policies and procedures for oversight of laboratories performing all laboratory testing covered by CLIA are equivalent to those required by our CLIA regulations in the matters of inspection, monitoring proficiency testing (PT) performance, investigating complaints, and making PT information available. The CAP submitted documentation regarding its requirements for monitoring and inspecting laboratories and describing its own standards regarding accreditation organization data management, inspection processes, procedures for removal or withdrawal of accreditation, notification requirements, and accreditation organization resources. We have determined that the requirements of the accreditation program submitted for approval are equal to or more stringent than the requirements of the CLIA regulations.

B. Subpart H--Participation in Proficiency Testing for Laboratories Performing Nonwaived Testing

We have determined that the CAP's requirements are equal to or more stringent than the CLIA requirements at §§ 493.801 through 493.865. Consistent with the CLIA requirements, all of the CAP's accredited laboratories are required to participate in an HHS-approved PT program for tests listed in subpart I. CLIA exempts waived testing from PT, whereas the CAP requires its accredited laboratories to participate in a PT program for test systems waived under CLIA.

C. Subpart J--Facility Administration for Nonwaived Testing

The CAP requirements are equal to or more stringent than the CLIA requirements at §§ 493.1100 through 493.1105. CAP is more stringent than CLIA in its specific requirements for the Laboratory Information System that include requirements for computer facility, hardware and software, system security, patient data, auto verification, data retrieval and preservation, interfaces, and telepathology.

D. Subpart K--Quality System for Nonwaived Testing

We have determined that the quality control requirements of the CAP are more stringent than the CLIA requirements at §§ 493.1200 through 493.1299. The CAP lists extensive requirements for the methodologies of clinical biochemical genetics, molecular pathology and flow cytometry, which are presented in separate checklists. The CAP's control procedure requirements for molecular testing and histocompatibility are more specific and detailed than the CLIA requirements for control procedures. Laboratories accredited by the CAP, performing waived testing must follow the same requirements that apply to non-waived testing for procedure manuals, specimen handling, results reporting, instruments, and equipment. Under CLIA, the subpart K Quality System requirements do not apply to waived testing.

E. Subpart M--Personnel for Nonwaived Testing

We have determined that the CAP requirements are equal to or more stringent than the CLIA requirements at §§ 493.1403 through 493.1495 for laboratories that perform moderate and high complexity testing. For certain types of testing, such as molecular testing, the experience requirements for General Supervisor are more closely related to the specific testing technology than the CLIA requirements. The CAP requires training and annual competency assessment for staff who perform waived testing. CLIA regulations do not contain such requirements for persons performing waived testing.

F. Subpart Q--Inspection

We have determined that the CAP inspection requirements are equal to or more stringent than the CLIA requirements at §§ 493.1771 through 493.1780. The CAP will continue to

conduct biennial onsite inspections. During the onsite inspection, the CAP requires that the inspector meet with the hospital administrator or medical staff to obtain their feedback on the laboratory service. The CAP also requires a mid-cycle self-inspection of all accredited laboratories. CLIA regulations do not contain these requirements.

G. Subpart R--Enforcement Procedures

We have determined that the CAP meets the requirements of subpart R to the extent that it applies to accreditation organizations. The CAP's policy sets forth the actions the organization takes when laboratories it accredits do not comply with its requirements and standards for accreditation. When appropriate, the CAP will deny, suspend, or revoke accreditation in a laboratory accredited by the CAP and report that action to us within 30 days. The CAP also provides an appeals process for laboratories that have had accreditation denied, suspended, or revoked.

We have determined that the CAP's laboratory enforcement and appeal policies are equal to or more stringent than the requirements of part 493 subpart R as they apply to accreditation organizations.

IV. Federal Validation Inspections and Continuing Oversight

The federal validation inspections of laboratories accredited by the CAP may be conducted on a representative sample basis or in response to substantial allegations of noncompliance (that is, complaint inspections). The outcome of those validation inspections, performed by CMS or our agents, or the state survey agencies, will be our principal means for verifying that the laboratories accredited by the CAP remain in compliance with CLIA requirements. This federal monitoring is an ongoing process.

V. Removal of Approval as an Accrediting Organization

Our regulations provide that we may rescind the approval of an accreditation organization, such as that of the CAP, for cause, before the end of the effective date of approval. If we determine that the CAP has failed to adopt, maintain and enforce requirements that are

equal to, or more stringent than, the CLIA requirements, or that systemic problems exist in its monitoring, inspection or enforcement processes, we may impose a probationary period, not to exceed 1 year, in which the CAP would be allowed to address any identified issues. Should the CAP be unable to address the identified issues within that timeframe, we may, in accordance with the applicable regulations, revoke the CAP's deeming authority under CLIA.

Should circumstances result in our withdrawal of the CAP's approval, we will publish a notice in the **Federal Register** explaining the basis for removing its approval.

VI. Collection of Information Requirements

This notice does not impose any information collection and record keeping requirements subject to the Paperwork Reduction Act (PRA). Consequently, it does not need to be reviewed by the Office of Management and Budget (OMB) under the authority of the PRA. The requirements associated with the accreditation process for clinical laboratories under the CLIA program, and the implementing regulations in 42 CFR part 493, subpart E, are currently approved under OMB control number 0938-0686.

VII. Executive Order 12866 Statement

In accordance with the provisions of Executive Order 12866, this notice was not reviewed by the Office of Management and Budget.

The Acting Administrator of the Centers for Medicare & Medicaid Services (CMS), Elizabeth Richter, having reviewed and approved this document, authorizes Lynette Wilson, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Dated: March 24, 2021.

Lynette Wilson,

Federal Register Liaison,

Centers for Medicare & Medicaid Services.

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